

Technical Evaluation Report for Dengue NSI Antigen Detection Kit by ELISA

	Technical Specifications	(Panbio Dengue NSI Early ELISA) (M/s Vandana Associates)	QUALISA Dengue NSI (M/s Qualpro Diagnostic)	Remark
1-	The ELISA kit should be designed for qualitative detection of dengue NSI Antigen of all 4 dengue serotypes in human serum	(Received confirmation from M/s Vandana Associates that there kit comprises of all 4 dengue serotypes in human serum	Not Mentioned	
2-	The kit should be provided with the following materials and reagents			
a-	Anti NSI Antibody coated Breakway Microwells (12 x 8 = 96 walls). Desiccant should be provided for storing the unused microwells which are to be resealed immediately.	Yes	Yes	
b-	Horseradish peroxidase conjugated Anti-NSI monoclonal antibody with preservatives	Yes	Yes	
c-	Chromogenic substrate in buffer	Yes	Yes	
d-	Positive control in the form of recombinant antigen with preservatives and antibiotics	Yes as per the specification	Yes but using stabilized human serum not recombinant antigen (not as per specification)	Panbio Dengue ELISA kit uses recombinant antigen for positive control thus making it less biohazard kit
e-	Negative Control in the	Yes as per the	Yes as per the	

	form of confirmed negative human serum with preservatives and antibiotics with preservatives and antibiotics	specification	specification	
f-	Calibrators in the form of recombinant antigen with preservatives and antibiotics	Yes as per the specification	No Calibrators	Not as per the specification
g-	Sample diluents	Yes	Yes	
h-	Wash buffer	Yes	Yes	
3-	The time required for performing the test for detection of dengue NSI antigen by ELISA should range between 2-4 hours.	Yes	Yes	
4-	The ELISA Kit for detection of dengue NSI antigen should have a sensitivity of >90% and a specificity of >95% taking RT-PCR as the gold standard	Yes as per the specification	Not mentioned but accordingly kit insert sensitivity 100% specificity 99% as per specification	
5-	The kit should have a shelf-life of a least 6 months when stored at an ambient temperature of 2°C - 8°C	Yes as per the specification	Not mentioned but accordingly to kit insert as per specification	Panbio ELISA kit have expiry up to 9-12 months provide customer longer usage time.
6-	Transportation should be under cold chain	Yes	Yes	
7-	Responsive/Non Responsive	Responsive	Non Responsive	