File No.GEM/TP/ Point of Care Diagnostic Test Kit - Dengue Rapid Test Kit/2019 (Version 3.0)										DRAFT T/P	
Level 1 Category : Laboratory and Measuring and Observing and Testing Equipment - UNSPS Code 41000000											
Level 2 Category : Measuring and observing and testing instruments - UNSPS Code 41110000											
Level 3 Category : Patient point of care testing supplies and equipment - UNSPS Code 41116200											
Level 4 Category : Point of Care Diagnostic Test Kit - Dengue Rapid Test Kits - UNSPS Code 41116290										GEM Version 3.0	
S.NO	PARAMETER	HINT	TYPE OF FIELD	VALUES					UNIT	CATEGORY OF FIELD	REMARKS
GENERAL FEATURES											
1	Product Description	--	ENUMERABLE	Dengue Rapid Test Kit					--	MANDATORY	
2	Clinical Purpose	--	ENUMERABLE	To provide early diagnosis of acute dengue infection					--	MANDATORY	
PRODUCT INFORMATION											
1	Detects	--	ENUMERABLE	IgM + IgG Antibodies to Dengue Virus	NS1 Ag to Dengue Virus from Day 1 of fever				--	GOLDEN	Multi Select
2	Type of Test	--	ENUMERABLE	Qualitative	Quantitative				--	MANDATORY, FILTER	
3	Testing Principle	--	ENUMERABLE	Lateral flow chromatographic immunoassay					--	MANDATORY	
4	Kit should be able to detect all the 4 serotypes of dengue viruses (DEN-1, DEN-2, DEN-3, and DEN-4).	--	ENUMERABLE	Yes					--	MANDATORY	
5	The test should be able to differentially detect IgG and IgM Antibodies against all 4 serotypes of Dengue virus	--	ENUMERABLE	Yes	NA for Ns1 Ag				--	MANDATORY	
6	Test should be able to give a presumptive differentiation between primary & secondary dengue infections	--	ENUMERABLE	Yes					--	MANDATORY	
7	Test should have no cross reactivity with other Flavivirus group mediated and mosquitoes-borne disease	--	ENUMERABLE	Yes					--	MANDATORY	
8	Specimen required for testing	--	ENUMERABLE	Whole Blood	Serum	Plasma				MANDATORY, FILTER	Multi Select
9	Result Time (min)	--	ENUMERABLE	5-10	10-20	20-30			Minutes	MANDATORY, FILTER	
10	Ability to Evaluate Negative or Positive test result	--	ENUMERABLE	Yes					--	MANDATORY	
11	Sensitivity for Dengue NS1 Ag (%)	--	ENUMERABLE	≥ 95%	NA for IgM/IgG				--	MANDATORY	
12	Specificity Dengue NS1 Ag (%)	--	ENUMERABLE	≥ 99%	NA for IgM/IgG				--	MANDATORY	
13	Sensitivity for Dengue IgM/IgG Antibody (%)	--	ENUMERABLE	≥ 94%	NA for Ns1 Ag				--	MANDATORY	
14	Specificity Dengue IgM/IgG Antibody (%)	--	ENUMERABLE	≥ 96%	NA for Ns1 Ag				--	MANDATORY	
15	Contains an internal control line for the confirmation that the test has been performed correctly	--	ENUMERABLE	Yes					--	MANDATORY	
16	Storage temperature	--	ENUMERABLE	2^0C to 30^0C					--	MANDATORY	
17	The supplier should ensure maintenance of recommended temperature during storage and transportation of Kit	--	ENUMERABLE	Yes					--	MANDATORY	

18	The kit should comply with all provisions of Drugs and cosmentics Act, 1940 and applicable rules there under	--	ENUMERABLE	Yes					--	MANDATORY	
KIT CONTENTS											
1	Main item in test kit for performing the test	--	ENUMERABLE	Card					--	MANDATORY	
2	Sample Dropper Provided with each card	--	ENUMERABLE	Yes					--	MANDATORY	
3	Dessicant to absorb moisture so that the Card do not get spoiled provided with each card	--	ENUMERABLE	Yes					--	MANDATORY	
4	Sample Diluent/Assay Buffer Provided	--	ENUMERABLE	Yes					--	MANDATORY	
5	Packaging insert in English detailing the principle, components, methodologies, validity criteria, performance characteristics,bio-safety, limitations of assay, storage condition, manufacturing and expiry dates and methods of disposal Provided with each kit	--	ENUMERABLE	Yes					--	MANDATORY	
6	Reactive and non reactive controls provided with each kit in adequate volume (minimum 10% of pack size)	--	ENUMERABLE	Yes	No				--	GOLDEN	
7	Individualy packed sterile disposable lancets and disposable alcohol swabs provided with each test kit	--	ENUMERABLE	Yes	No				--	GOLDEN	
8	Other accessories and spares provided if any for standard pack in the kit	Must Declare	TEXT						--	MANDATORY	AKBNV
PACKAGING											
1	Pack Size	--	ENUMERABLE	10 Tests Pack, 20 Tests pack, 25 Tests pack, 30 Tests pack, 40 Tests Pack, 50 Tests Pack					--	GOLDEN	
2	The packing and labelling should be as per Drugs and Cosmetics Act, 1940 and applicable rules there under	--	ENUMERABLE	Yes					--	MANDATORY	
3	Each card (cassette) should have space for patients particulars and date of the test	--	ENUMERABLE	Yes					--	MANDATORY	
4	The test kit should be packed in such a way that there is proivision to conduct single test at a time	--	ENUMERABLE	Yes					--	MANDATORY	
5	Each test kit should be indivdually packed in a hermetically sealed and non-permeable pouch	--	ENUMERABLE	Yes					--	MANDATORY	
CERTIFICATIONS & REPORTS											
1	The kit should have approval of the statutory authority in its country of origin	--	ENUMERABLE	Yes					--	MANDATORY	
2	The Kit should be registered and licensed in India by DCGI in case of imported kits (Proof of the same to be submitted to buyer on demand)	--	ENUMERABLE	Yes	NA for domestically manufactured kits				--	MANDATORY	
3	Availability of valid drug license from competent authority defined under Drugs and Cosmetics Act, 1940 (Proof of the same to be submitted to buyer on demand)	--	ENUMERABLE	For Manufacture to sale	For sale or distribution				--	MANDATORY, FILTER	Multi Select
4	Drug License Number	Must Declare	TEXT						--	MANDATORY	AKBNV
5	Drug License Date	Must Declare	TEXT						--	MANDATORY	AKBNV
6	Manufacturer certifications (Proof of the same to be submitted to the buyer on demand)	--	ENUMERABLE	GMP	WHO GMP				--	MANDATORY, FILTER	Multi Select

7	GMP/ WHO GMP Certification Number	Must Declare	TEXT						--	MANDATORY	AKBNV
8	GMP/ WHO GMP Certification Date	Must Declare	TEXT						--	MANDATORY	AKBNV
9	ISO 13485 Certified Manufacturer (Proof of the same to be submitted to buyer on demand)	--	ENUMERABLE	Yes					--	MANDATORY	
10	Product Certifications (Proof of the same to be submitted to buyer on demand)	--	ENUMERABLE	EU-CE (IVD)	US-FDA				--	MANDATORY, FILTER	Multi Select
11	Availability of Test report from Central GOVT/NABL/ILAC accredited Lab to prove the conformity to the declared specification(proof of the same to be submitted to the buyer on demand)	--	ENUMERABLE	Yes					--	MANDATORY	
12	Availability of Performance Evaluation Report (Proof of the same to be submitted to the buyer on demand)	--	ENUMERABLE	Yes					--	MANDATORY	
13	Performance Evaluation Report issuing body	--	ENUMERABLE	National Insitute of Biological Sciences	National Centre for Disease Control	Any other govt approved lab				MANDATORY, FILTER	
14	Name of the Performance Evaluation Report issuing body if other than specified institutes	Must Declare	TEXT						--	MANDATORY	AKBNV
SHELF LIFE											
1	Shelf Life (in months)	--	NUMERIC	24	30	36			Months	GOLDEN	
2	The product should not have passed more than 1/6 of the total shelf life at the time of dispatch to the consignee	--	ENUMERABLE	Yes					--	MANDATORY	

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ACEO