File No.GEM/TP/Point of Care Diagnostic Test Kit - Enterovirus Rapid Test Kit/2018 (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 - Enterovirus Rapid Test Kit - UNSPS Code 41116293									GEM Version 3.0	
S.NO	**PARAMETER**	**HINT**	**TYPE OF FIELD**	**VALUES**					**UNIT**	**CATEGORY OF FIELD**	**REMARKS**
GENERAL FEATURES											
1	Product Description	--	ENUMERABLE	Enterovirus Rapid Test Kit					--	MANDATORY	
2	Clinical Purpose	--	ENUMERABLE	To detect antibodies to human Enterovirus 71 in serum, plasma or whole blood samples					--	MANDATORY	
3	Detects	--	ENUMERABLE	IgM Antibodies to Enterovirus 71		IgG Antibodies to Enterovirus 71			--	GOLDEN	Multi Select
4	Type of Test	--	ENUMERABLE	Qualitative	Quantitative				--	MANDATORY, FILTER	
5	Testing Principle	--	ENUMERABLE	Immuno-chromatographic Principle					--	MANDATORY	
6	Specimen Required for testing	--	ENUMERABLE	Whole Blood	Serum	Plasma				MANDATORY, FILTER	Multi Select
7	Result Time (min)	--	ENUMERABLE	5-10	10-15	15-20	20-25	25-30	Minutes	MANDATORY, FILTER	
8	Ability to Evaluate Negative or Positive test result	--	ENUMERABLE	Yes					--	MANDATORY	
9	Sensitivity (%)	--	NUMERIC	90 -100					--	MANDATORY	
10	Specificity (%)	--	NUMERIC	90 -100					--	MANDATORY	
11	Contains an internal control line for the confirmation that the test has been performed correctly	--	ENUMERABLE	Yes					--	MANDATORY	
12	Storage temperature	--	ENUMERABLE	2^0C to 8^0C	2^0C to 30^0C				--	MANDATORY, FILTER	
13	The supplier should ensure maintenance of recommended temperature during storage and transportation of Kit	--	ENUMERABLE	Yes					--	MANDATORY	
14	The kit should comply with all provisions of Drugs and cosmentics Act, 1940 and Rules, 1945	--	ENUMERABLE	Yes					--	MANDATORY	
KIT CONTENTS											
1	Main items in test kit for performing the test	--	ENUMERABLE	Card					--	MANDATORY	
2	Clean, dry sterilized sample dilution tubes with sample diluent present with each kit	--	ENUMERABLE	Yes					--	MANDATORY	
3	Sample Dropper Provided	--	ENUMERABLE	Yes					--	MANDATORY	
4	Dessicant to absorb moisture so that the Card/Strip do not get spoiled	--	ENUMERABLE	Yes					--	MANDATORY	
5	Reactive and non reactive controls provided with each kit in adequate volume (minimum 10% of pack size)	--	ENUMERABLE	Yes	No				--	GOLDEN	
6	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	
7	Other accessories and spares provided if any for standard pack in the kit	Must Declare	TEXT						--	MANDATORY	

PACKAGING											
1	Pack Size	--	ENUMERABLE	10 Tests Pack, 20 Tests pack, 25 Tests pack, 30 Tests pack, 50 Tests Pack, 100 Tests pack					--	GOLDEN	
2	The packing and labelling should be as per Drugs and Cosmetics Act, 1940	--	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 moisture proof pouches	--	ENUMERABLE	Yes					--	MANDATORY	
6	Test Kit container for housing all the items in the kit	--	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 (Proof of the same to be submitted to buyer on demand)	--	ENUMERABLE	Yes					--	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 Manufacturing	For Selling				--	MANDATORY, FILTER	Multi Select
4	Drug License Number	Must Declare	TEXT						--	MANDATORY	
5	Drug License Date	Must Declare	TEXT						--	MANDATORY	
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	
8	GMP/WHO GMP Certification Date	Must Declare	TEXT						--	MANDATORY	
9	ISO 13485 Certified Manufacturer (Proof of the same to be submitted to buyer on demand in Certification is available)	--	BOOLEAN	Yes	No				--	MANDATORY, FILTER	
10	Product Certifications (Proof of the same to be submitted to buyer on demand)	--	ENUMERABLE	EU-CE	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		Any other govt approved lab			--	MANDATORY, FILTER	
14	Name of the Performance Evaluation Report issuing body if other than National Institute of Biological Sciences	Must Declare	TEXT						--	MANDATORY	
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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