

File No.GEM/TP/ Point of Care Diagnostic Test Kit - Typhoid 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 - Typhoid Rapid Test Kit - UNSPS Code 41116298										GEM Version 3.0	
S.NO	PARAMETER	HINT	TYPE OF FIELD	VALUES				UNIT	CATEGORY OF FIELD	REMARKS	
<b>GENERAL FEATURES</b>											
1	Product Description	--	ENUMERABLE	Typhoid Rapid Test Kit				--	MANDATORY		
2	Clinical Purpose	--	ENUMERABLE	To detect antibodies to Salmonella typhi in human serum or plasma				--	MANDATORY		
3	Detects	--	ENUMERABLE	IgM Antibodies to salmonella typhi	IgG Antibodies to salmonella typhi			--	MANDATORY, FILTER	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)	--	MEASURABLE	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	--	BOOLEAN	Yes	No				--	GOLDEN	
12	Storage temperature	--	ENUMERABLE	2°C to 8°C	2°C to 30°C				--	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 cosmetics Act, 1940 and Rules, 1945	--	ENUMERABLE	Yes					--	MANDATORY	
<b>KIT CONTENTS</b>											
1	Main items in test kit for performing the test	--	ENUMERABLE	Card	Strip				--	GOLDEN	Multi Select
2	Sample Dropper Provided with each card	--	ENUMERABLE	Yes					--	MANDATORY	
3	Sample Diluent/Assay Buffer Provided	--	ENUMERABLE	Yes					--	MANDATORY	
4	Dessicant to absorb moisture so that the Card do not get spoiled	--	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	Clean, dry sterilized sample collection container present with the kit	--	BOOLEAN	Yes	No				--	GOLDEN	
8	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 provision to conduct single test at a time	--	ENUMERABLE	Yes					MANDATORY	
5	Each test kit should be individually 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	--	Yes						MANDATORY	