File No.GEM/TP/ Point of Care Diagnostic Test Kit - HBsAg Rapid Test Kits/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 Kits - Hepatitis B Surface Antigen (HBsAg) Rapid Test Kits - UNSPS Code 41116288											GEM Version 3.0	
S.NO	PARAMETER	HINT	TYPE OF FIELD	VALUES						UNIT	CATEGORY OF FIELD	REMARKS
GENERAL FEATURES												
1	Product Description	--	ENUMERABLE	Hepatitis B Surface Antigen (HBsAg) Rapid Test Kits						--	MANDATORY	
2	Clinical Purpose	--	ENUMERABLE	To provide diagnosis of Hepatitis B Virus infection						--	MANDATORY	
PRODUCT INFORMATION												
1	Detects	--	ENUMERABLE	Hepatitis B Surface Antigen (HBsAg)						--	MANDATORY	
2	Should be solid phase/ particle coated with monoclonal antibodies to HBsAg	--	ENUMERABLE	Yes						--	MANDATORY	
3	Test Should be able to detect all 11 subtype of HBsAg	--	ENUMERABLE	Yes						--	MANDATORY	
4	Test can be performed on	--	ENUMERABLE	Whole Blood	Serum	Plasma				--	MANDATORY, FILTER	Multi Select
5	Type of Test	--	ENUMERABLE	Qualitative	Quantitative					--	GOLDEN	
6	Testing Principle	--	ENUMERABLE	Lateral flow chromatographic immunoassay		Immunofiltration				--	GOLDEN	
7	Result Time (min)	--	ENUMERABLE	5-10	10-20	20-30				Minutes	MANDATORY, FILTER	
8	Ability to Evaluate Negative or Positive test result	--	ENUMERABLE	Yes						--	MANDATORY	
9	Sensitivity (%)	--	MEASURABLE	95-100						--	MANDATORY	
10	Specificity (%)	--	MEASURABLE	95-100						--	MANDATORY	
11	Contains an internal control line/dot for the confirmation that the test has been performed correctly	--	ENUMERABLE	Yes						--	MANDATORY	
12	Storage temperature	--	ENUMERABLE	2^0C to 30^0C						--	MANDATORY	
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 applicable rules there under	--	ENUMERABLE	Yes						--	MANDATORY	
KIT CONTENTS												
1	Main items in test kit for performing the test	--	ENUMERABLE	Card	Strip					--	MANDATORY, FILTER	Multi Select
2	Sample Dropper Provided with each card/strip	--	ENUMERABLE	Yes						--	MANDATORY	
3	Dessicant to absorb moisture so that the Card/Strip 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, FILTER	
3	Indigenous manufacturers should be licensed by the competent authority defined under Drugs and Cosmetics act 1940	--	ENUMERABLE	Yes	NA for imported kits				--	MANDATORY, FILTER	
4	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
5	Drug License Number	Must Declare	TEXT						--	MANDATORY	AKBNV
6	Drug License Date	Must Declare	TEXT						--	MANDATORY	AKBNV
7	Manufacturer certifications (Proof of the same to be submitted to the buyer on demand)	--	ENUMERABLE	GMP	WHO GMP				--	MANDATORY, FILTER	Multi Select
8	GMP/ WHO GMP Certification Number	Must Declare	TEXT						--	MANDATORY	AKBNV
9	GMP/ WHO GMP Certification Date	Must Declare	TEXT						--	MANDATORY	AKBNV
10	ISO 13485 Certified Manufacturer (Proof of the same to be submitted to buyer on demand)	--	ENUMERABLE	Yes					--	MANDATORY	
11	Product Certifications (Proof of the same to be submitted to buyer on demand)	--	ENUMERABLE	EU-CE (IVD)	US-FDA				--	MANDATORY, FILTER	Multi Select
12	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	
13	Availability of Performance Evaluation Report (Proof of the same to be submitted to the buyer on demand)	--	ENUMERABLE	Yes					--	MANDATORY	
14	Performance Evaluation Report issuing body	--	ENUMERABLE	National Insitute of Biological Sciences	Any other govt approved lab					MANDATORY, FILTER	

15	Name of the Performance Evaluation Report issuing body if other than specified institute	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