

Doc Name:	Material Safety Data Sheet (MSDS) for Quantiplus® HBV FAST Detection Kit (Real-Time Qualitative PCR Kit)		
Doc No.	MSDS/HL/007	Ver No:00	Effective from: 1/11/23

1	Company identification	HLSS Manufacturing Pvt Ltd Plot No's M14, M15, M16, TSIIC Medical device park Sulthanpur villiage, Ameenpur Mandal, Sangareddy Dist, TS-502319 Emergency Contact Tel: +91-08413-232256/ +91 9052226226	
		Email: <u>info@huwellifesciences.com</u> http://www.huwellifesciences.in	
2	Product identification		
2.1	Name of the Product	: Quantiplus® HBV FAST Detection Kit (Real-Time Qualitative PCR Kit)	
2.2	Product Code	: QLF-HBV-25 QLF-HBV-50 QLF-HBV-100	
2.3	Pack size (No. of rxns)	: 25 Tests, 50 Tests, 100 Tests	
2.4	Intended use:	Quantiplus® HBV FAST Detection Kit is a Real-Time PCR based in vitro diagnostic assay for detection of Hepatitis B Virus in human plasma. The kit contains qPCR mix with UDG/UNG, Primer Probe Mix (PPM), Positive control (HBVFPC) and Internal Control (IC-B mix). This advanced formulation enables performance of fast PCR in shorter run time (≤60 min), and UDG/UNG helps in controlling PCR carryover contamination. This kit is not to be used for screening of blood/blood products from blood donors.	
2.5	Composition/	The product contains general buffer, dNTP's, amplification mix, primer and	
	Information on	probes and MgCl ₂ with non-hazardous properties.	
	reagents:	Note : This product must be used for Invitro Diagnostic Use only. This product must be used by scientists/ laboratory technicians with strong knowledge on molecular biology as per Good Laboratory practice (GLP) and product insert/ instruction manual.	
3	Hazards identification	Significant health effects are not anticipated from routine use of this kit	
	identification	when following the precautions listed within this MSDS and the kit specific package insert. None of the components listed within this kit are considered hazardous as defined by the Occupational Safety and Health Administration (OSHA).	
		OSHA Hazards	: No Known OSHA Hazards
		Inhalation Ingestion	: No information available. : May be harmful.
		Skin Contact	: No information available.
		Eye Contact	: May cause irritation.
4	First-Aid Measures	For all incidents, a medical exam is desirable	
		Skin Contact : Wash copious	on available. mmediate vomiting, seek medical advice sly with water and soap. opiously with water and seek medical advice

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5	Fire-fighting Measures	Extinguishing media: Use any mean suitable to extinguish the surrounding fire Un-extinguishing media: No information available Special hazards of product: No information available Protective equipment For fire fighting: Carry an autonomous respiratory protection apparatus and appropriate protection clothes	
6	Accidental release Measures	Individual Precaution: Use an individual protection equipment Environmental Precaution: If incident, let flow run copiously Method of cleaning: Clean with an inert absorbent	
7	Handling and storage	No specific recommendation is requested. Always store in frozen condition, Observe all conditions described in the user manual and on the labels. As with all chemical and biological substances, avoid getting the components within this kit spilled on you or into your body. Do not eat or drink while using this kit. This kit should be handled only by qualified clinical or laboratory employees trained on the use of this kit and who are familiar with the potential hazards. Universal precautions to be followed when handling and working with this kit.	
8	Exposure controls		
8.1	Exposure limits	: No information available	
9	Personnel Protection	Respiratory protection: No information available Hands protection: Wear water-proof gloves Eyes protection: Use chemical safety goggles Skin protection: Wear lab coat Hygiene measures: Follow good laboratory hygiene practices and security Instructions	
10	Physical and Chemical properties		
10.1	Physical state	: Liquid Chemical, physical, and toxicological properties have not been thoroughly investigated	
11	Stability and reactivity	Stability: Stable under conditions described in the Product insert Materials to avoid: No information available Hazardous decomposition Products: No information available	
12	Toxicological information	Potential effects on health Eyes : No information available Skin : No information available Inhalation : No information available Ingestion : No information available Special Effects	

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		Carcinogen	: No information available
		Mutagen	: No information available
		Toxicity for reproduction	: No information available
		Sensitization	: No information available
13	Ecological	Mobility	: No information available
	information	Persistence/degradation	: Intrinsically biodegradable
		Bioaccumulation	: No information available
		Aquatic Toxicity	: No information available
		Disposal Considerations & requirements : Dispose in accordance with	
		state and local regulations	
14	Transportation	The product is not dangerous. Follow IATA regulations	
	information		
15	Regulatory	No information available	
	information		
16	Other Information	HLSS Manufacturing Pvt Ltd assumes no liability for damages resulting from handling or being in contact with this product. Customer is solely responsible for improper usage of this product other than for what this product is designed to use. The kit and its components may present unknown hazards and should be used with caution. Improper use and/or inappropriate combination with other products and substances may produce harmful results.	
-End-			