

## MBPCR149

## Hi-PCR<sup>®</sup> Hepatitis B Virus (HBV) Probe PCR Kit

### Description

Hepatitis B is an infectious disease of liver caused by the Hepatitis B virus (HBV), which is a small DNA virus. It belongs to Hepadnaviridae family and is classified into 10 genotypes, A to J. Each genotype has a distinct geographic distribution. This virus can cause both acute and chronic infections of the liver. It is transmitted when blood or mucous membranes are exposed to infectious blood and body fluids. Other risk factors include working in healthcare, blood transfusions, dialysis, etc. Many people have no symptoms during the initial infection, but some develop a rapid onset of sickness with vomiting, yellowish skin, tiredness, dark urine and abdominal pain. It may take 30 to 180 days for symptoms to begin. Early symptoms of the infection include appetite loss, vomiting and abdominal symptoms, with approximately 10-20% of those patients developing fever as well as rheumatoid joint and muscle pain. Jaundice, which may be accompanied by itching, will then develop within 2-14 days. Fulminant hepatitis then occurs in about 1% of all infected patients, which in severe cases may be fatal. Of those individuals infected by HBV, 5-10% are likely to develop chronic liver inflammation which may progress to cirrhosis of the liver or, in the worst case, primary liver cell carcinoma. Chronic Hepatitis may progress to scarring of the liver, liver failure, or liver cancer. Hence, early diagnosis and treatment of Hepatitis is important which can also contribute to reducing Hepatitis transmission.

**NOTE:** HiMedia's Hi-PCR<sup>®</sup> Hepatitis B Virus (HBV) Probe PCR Kit is for *in vitro* use only.

### Intended Use

Hi-PCR<sup>®</sup> Hepatitis B Virus (HBV) Probe PCR Kit is intended for use by qualified clinical laboratory personnel trained in the techniques of real-time PCR and *in vitro* diagnostic procedures. The kit is recommended for sensitive and specific detection of HBV DNA in human plasma samples. The Hi-PCR<sup>®</sup> Hepatitis B Virus (HBV) Probe PCR Kit targets 100% of the known HBV genotypes (HBV genotype A-J).

### Product Description:

Hi-PCR<sup>®</sup> Hepatitis B Virus (HBV) Probe PCR Kit is based on real-time PCR technology for the detection of Hepatitis B Virus (HBV) specific DNA encompassing all major HBV genotypes (HBV genotype A-J). The kit contains primer-probe mixture specific for detection of HBV DNA. In addition, the kit can identify the DNA extraction efficiency and ensure successful PCR reaction with the help of an endogenous internal control. The kit also provides positive control for the validity of the assay. The assay principle is based on hydrolysis probe chemistry which confers higher specificity and sensitivity.

### Positive control

This is a control reaction used to test for the presence of inhibitors in the sample or the efficiency of the polymerase chain reaction itself using a pre-dispensed DNA sequence and the primer set that detects it. It is usually used to ensure proper and intended functioning of all the reagents and is recommended to be used in every run to assess optimal performance.

### Endogenous Internal control

This is a control sequence that should amplify in all clinical samples which indicates the presence of sufficient DNA from human gene indicating the specimen is of acceptable quality. An internal control also allows to check for possible PCR inhibition or reagent failure.



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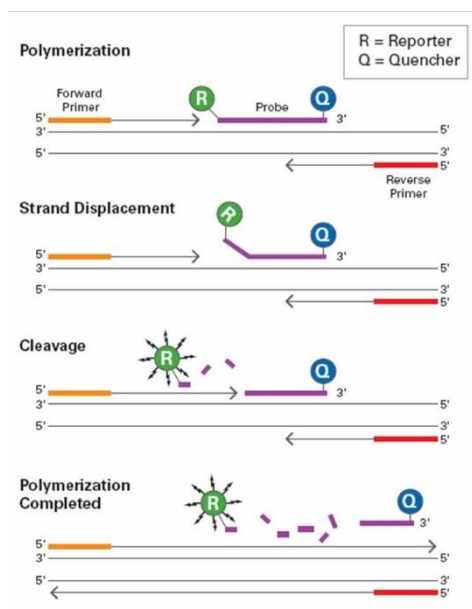
## Negative Template Control

A negative template control is needed to ensure that the reagents, equipment, and environment used in the assay are not contaminated with target DNA. In this reaction, Nuclease free water is used as the template. It is recommended to have a minimum of one reaction of negative template control per run.

## Principle

Real-Time polymerase chain reaction, also called quantitative Polymerase Chain Reaction (qPCR) or kinetic Polymerase Chain Reaction, is a laboratory technique based on the principle of PCR. This technique is used to amplify a targeted DNA sequence by use of hydrolysis probes that are short oligonucleotides that have a fluorescent reporter dye attached to the 5' end and a quencher dye to the 3' end. Hi-PCR® Hepatitis B Virus (HBV) Probe PCR Kit is designed to specifically detect **HBV viral DNA from subtypes A to J in FAM channel with Internal Control (IC) in ROX channel.**

## Diagrammatic representation of preferential binding of probe specific to DNA fragments in Real-time PCR



While the probe is intact, the proximity of the quencher dye greatly reduces the fluorescence emitted by the reporter dye by fluorescence resonance energy transfer (FRET). The probes are designed such that they anneal within a DNA region amplified by a specific set of primers. During PCR amplification, these probes will hybridize to the target sequences located in the amplicon i.e. the DNA. As the *Taq* DNA polymerase replicates the template with the bound probe, the 5'-nuclease activity of the polymerase enzyme cleaves the fluorescent probe. The end result in cleavage of the probe is separation of the reporter dye from the quencher dye and increasing the reporter dye signal. As the probe is removed from the target strand, primer extension continues to the end of the template strand. Hence, fluorescence detected in the quantitative PCR thermal cycler is directly proportional to the fluorophore released and the amount of DNA template present in the PCR. Thus, inclusion of the probe does not inhibit the overall PCR process.

## Molecular Features

- Detection of HBV subtypes A to J.
- Sensitive and specific.

## Technology features:

- Fast and reliable results within 90 minutes.
- Includes all reagents & controls for validity of the test.
- Open system – Compatible with 4-channel and 5-channel qPCR cyclers.
- Wet-lab assays validated on the Bio-Rad CFX Opus 96, Applied Biosystems QuantStudio 5 and Insta Q96® Plus Real Time PCR Systems.

## Types of Specimens and storage:

The internal validation of the Hi-PCR® Hepatitis B Virus (HBV) Probe PCR Kit was performed using DNA extracted from human EDTA plasma samples. Other sample materials are not validated. Therefore, we

recommend the use of EDTA plasma sample for detection of HBV. The DNA should be extracted using a standard viral DNA extraction kit. After collection, specimens may be stored at room temperature (15-25°C) for up to 8 hours or refrigerated (2–8°C) for up to 48 hours. Specimens stored beyond these time points must be frozen at or below -20 °C. Frozen specimens should undergo no more than one freeze-thaw cycle. After extraction, store the extracted DNA samples at -20°C for short period storage and -70°C or -80°C for long period storage.

### Specimen Handling

Follow appropriate techniques for handling specimens; after use, contaminated materials must be sterilized by autoclaving before discarding. Standard precautions as per established guidelines should be followed while handling clinical specimens and items contaminated with other body fluids. Safety guidelines may be referred in individual safety data sheets.

### Storage and Shelf life

The provided kit has a shelf-life of 12 months when stored between -10°C to -20°C. Repeated thawing and freezing of PCR reagents (< 10 freeze-thaw cycle) should be avoided, as this may reduce the sensitivity of the assay. If the reagents are to be used multiple times, we recommend storing reagents as aliquots to avoid repeated freeze and thaw. Degradation of sample DNA specimens can also reduce the sensitivity of the assay. HiMedia Laboratories does not recommend using the kit after the expiry date stated on the pack.

### Kit Contents

The provided PCR kit contains:

Components	Product code	Reagents provided for (reactions)*		
		25R	50R	100R
HBV Master Mix	DS1551	135 µL	270 µL	530 µL
HBV Primer-Probe Mix	DS1304	27 µL	54 µL	106 µL
HBV Positive Control Mix	DS1753	76 µL	151 µL	297 µL
Molecular Biology Grade Water for PCR	ML065	135 µL	151 µL	297 µL

\* For a 20 µL PCR reaction

### Materials needed but not provided

- Appropriate real-time PCR instrument.
- Appropriate nucleic acid extraction system or kit.
- Centrifuge with a rotor for 1.5ml - 2 ml reaction tubes.
- Centrifuge with a rotor for microtiter plates, if using 96 well reaction plates.
- Vortex mixer.
- PCR tubes (0.1ml or 0.2ml) or 96 well reaction plates with corresponding (optical) closing material or lid.
- Pipettes (Capacity: 0.5 - 10 µL/10 - 100 µL/20 - 200 µL/100 - 1000 µL).
- Pipette tips with filters (As per pipette capacity).
- Powder-free gloves (disposable).

All materials are available through [www.himedialabs.com](http://www.himedialabs.com)

Product name	Product Code
<b>Real-Time PCR Instrument and equipment</b>	
Insta Q96® AG Real time PCR System, 96 well block, 5 channels	MBLA027
Insta Q96® AG 6.0 Real time PCR System, 96 well block, 6 channels	MBLA028
Insta Q96® Plus Real time PCR System, 96 well block, 5 channels	LA1073
Insta Q96® - 6.0 Real time PCR System, 96 well block, 6 channels	LA1074
Insta Q96® Real time PCR System, 96 well block, 5 channels	LA1012
Insta Q48® M4 Real time PCR System, 96 well block, 4 channels	LA1023
Insta Q48® M2 Real time PCR System, 96 well block, 2 channels	LA1024
TabSpin™ Microcentrifuge	LA1089/LA1090
HiPer® Mini Plate Centrifuge	LA1099

<b>Automated nucleic acid extraction system and materials</b>	
Insta NX <sup>®</sup> Instrument - fully automated nucleic acid purification system utilizing the Innovative Super -S membrane column method	LA1056
Insta NX <sup>®</sup> Mag16, Insta NX <sup>®</sup> Mag16 <sup>Plus</sup>	LA1118, MBLA018
Insta NX <sup>®</sup> Mag32, Insta NX <sup>®</sup> Mag32 <sup>Plus</sup>	LA1096, MBLA019
Insta NX <sup>®</sup> Mag96, Insta NX <sup>®</sup> Mag96plus	LA1097, MBLA026
<b>Extraction Kits</b>	
HiPurA <sup>®</sup> Pre-filled Cartridges for Viral Nucleic Acid Purification	MB582PC16
HiPurA <sup>®</sup> Pre-filled Plates for Viral Nucleic Acid Purification	MB582MPF16
HiPurA <sup>®</sup> Pre-filled Plates for Viral Nucleic Acid Purification [For Insta NX <sup>®</sup> Mag32]	MB582MPF-32
HiPurA <sup>®</sup> Prefilled Plates for Viral Nucleic Acid Purification [For Insta NX <sup>®</sup> Mag96]	MB582MPF-96
HiPurA <sup>®</sup> Viral DNA/RNA Purification Kit	MB582
HiPurA <sup>®</sup> Viral DNA Purification Kit	MB575
Insta NX <sup>®</sup> Viral DNA Purification Kit	MBIN015
<b>Tubes, plates, and other consumables</b>	
Varivol II Micropipettes (Capacity: 0.5 to 10 µL/10 to 100 µL/200 to 1000 µL)	LA611/LA614/LA615
µPet Autoclavable Micropipettes (Capacity: 0.5 - 10 µL/10 - 100 µL/20 - 200 µL/100 - 1000 µL)	LA955/LA958/LA959/LA960
Q4Pet Autoclavable Micropipette (Capacity: 0.5 to 10 µL/10 to 100 µL/100 - 1000 µL)	MBLA009/MBLA011/MBLA008
Barrier Tips, Maximum capacity 10 µL	LA749A
Barrier Tips, 100µl Max capacity 100 µL	LA1104A
Barrier Tips, Maximum capacity 200 µL	LA751A
Barrier Tips, Maximum capacity 1000 µL	LA859A
8-strip tubes & optically clear flat caps for PCR	PR17, PR22, PR23
PCR Tubes, 0.1 mL, 0.2 mL; PCR Plates	PW1255/PR2/PR3/PR19
Optical Sealing film	PR18
1.5 ml nuclease free Micro centrifuge tubes	PW146

#### Kit compatibility with Real-Time PCR Systems

Hi-PCR<sup>®</sup> Hepatitis B Virus (HBV) Probe PCR Kit contains fluorophores that are compatible to the following PCR systems:

<b>Real-Time PCR system</b>	<b>Company</b>	<b>Dye 1 (HBV)</b>	<b>Dye 2 (IC)</b>
Insta Q96 <sup>®</sup> AG/ Insta Q96 <sup>®</sup> AG 6.0/Insta Q96 <sup>®</sup> - 6.0/Insta Q96 <sup>®</sup> Plus/Insta Q48 <sup>®</sup> M4	HiMedia Laboratories Pvt. Ltd.	FAM	ROX
QuantStudio™ 3 and 5	Applied Biosystems	FAM	ROX
Applied Biosystems 7500	Applied Biosystems	FAM	ROX
BioRad CFX Opus 96/CFX96	Bio-Rad Laboratories, Inc.	FAM	ROX
Rotor-Gene <sup>®</sup> Q/QIAquant	QIAGEN	Green	Orange
Roche LightCycler <sup>®</sup> 96	Roche	FAM	ROX
AriaMx	Agilent	FAM	ROX
Alta RT-96/48	Athenese-Dx Private Limited	FAM	ROX
qTOWER <sup>3</sup> auto	Analytik Jena	FAM	ROX

**Note:** Ensure that the Real-Time PCR system is calibrated for dyes and is maintained according to the manufacturer's instructions and recommendations

### General Preparation Instructions

- Before use all PCR components should be completely thawed on ice (4°C).
- Perform the amplification reactions in a clean area, preferably in a biosafety cabinet.
- Use of aerosol barrier pipette tips is recommended to reduce contamination risks from extraneous DNA templates.
- Extract and store positive control sample (if used) separately from all other reagents to avoid contamination and add it to the reaction mix in a separate area.
- Clear surfaces and working areas with DNA Kil™ (ML221).

### Protocol for PCR Reaction Mix Preparation

1. In the “Master mix Preparation” area, thaw all components from the kit on ice, mix by inverting the tubes and centrifuge the reagents for 5 seconds. Keep on ice for later use.
2. Based on the number of specimens to be tested (N), calculate the volume of the components to be added as N X (volume of “1X”)
3. Use 1.5 mL Nuclease free centrifuge tube(s) for the preparation of the PCR reaction mix. Refer the following table. After all the reagents are added, mix them thoroughly and centrifuge for 5 seconds.

Components	Product code	Volume for “1X” (One Reaction)
<b>Preparation of PCR Reaction Mix</b>		
HBV Master Mix	DS1551	5 µL
HBV Primer-Probe Mix	DS1304	1 µL
<b>Total PCR Reaction Mix</b>	-	<b>6 µL</b>
<b>Template addition</b>		
Template/ Purified Viral DNA	-	14 µL
<b>Total reaction volume</b>	-	<b>20 µL</b>

4. Aliquot 6 µL of PCR reaction mix into respective labeled 0.1/0.2mL PCR tube/plate/strips, compatible to the PCR instrument to be used.
5. In the “Nucleic acid handling” area, add 14 µL of extracted DNA of test specimen into the plate/strip to respective wells.
6. For positive and no template control, template Viral DNA is replaced by Positive control for positive control reaction and by nuclease free water for no template control reaction. Refer the following table.

<b>Set up of controls for the PCR run</b>			
Components	Product code	Volume for “1X” (One Reaction)	
		Positive Control	No Template Control
Total PCR Reaction Mix		6 µL	6 µL
HBV Positive Control Mix	DS1753	14 µL	-
Molecular Biology Grade Water for PCR	ML065	-	14 µL
<b>Total reaction volume</b>	-	<b>20 µL</b>	<b>20 µL</b>

7. Tightly cap the tubes/strips or seal the plate using an optically clear adhesive film.
8. Centrifuge the tube briefly at 6000 rpm for about 10 seconds.
9. Place the tubes in Real-time PCR machine and set the recommended PCR program (mentioned below). Interpret the data from the amplification plot (observe the Ct values).

### Recommended PCR program

Step	Temperature	Time	Sampling	Cycles
1	95°C	10 minutes	---	1
2	95°C	05 seconds	---	45
3	55°C	45 seconds	Yes	
4	72°C	15 seconds	---	

### Selection of channel

Target	Dye	Quencher <sup>#</sup>
HBV	FAM	None
IC	ROX/Texas Red	None

§Passive Reference Dye: Select “None”

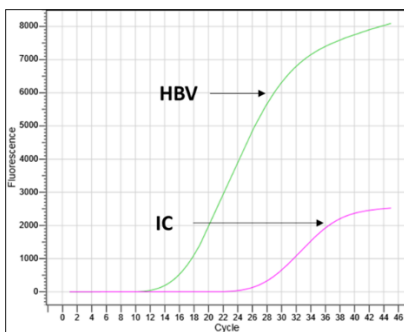
(#, §Thermo Fisher’s QuantStudio™ 5 Real-Time PCR System)

### Data Analysis

The following conditions should be met for a valid diagnostic test:

Control	Detection channel	
	FAM (HBV)	ROX (Internal Control)
HBV Positive Control	+	+
Negative Template Control	-	-

### Amplification Plots



Sr. No.	Sample	Ct Values	
		Positive Control	Internal Control
1.	Hepatitis B Virus (HBV)	15.32	27.39
2.	No template control (NTC)	-	-

Image representing amplification plot of Hepatitis Virus B (HBV) and Internal control (IC) gene with Ct values using HiMedia’s Hi-PCR® Hepatitis B Virus (HBV) Detection Probe PCR Kit on InstaQ 96 series of instrument (Ct values provided in table are for representation only).

### Data Interpretation:

Interpret the results of the specimen as follows:

Detection Channel		Result Interpretation
FAM (HBV)	ROX (Internal Control)	
+	+/-*	HBV specific DNA detected
(Ct cut off ≤ 38)		
-	+	HBV specific DNA is not detected. Sample does not contain detectable amounts of HBV specific DNA.
-	-	PCR Inhibition or reagent failure. Retest the sample.

\*Detection of the IC in the ROX channel is not required for the positive results in the FAM channel. Presence of high HBV DNA load and/or PCR inhibitors in the original sample can lead to reduced or absence of internal control signal.

## Performance Characteristics

### Analytical sensitivity

#### Limit of Detection (LoD)

The analytical sensitivity or the Limit of Detection (LOD) of Hi-PCR® Hepatitis B Virus (HBV) Detection Probe PCR Kit is defined as the concentration of HBV DNA molecules that can be detected with a positivity rate of  $\geq 95\%$ . The analytical sensitivity for Hi-PCR® Hepatitis B Virus (HBV) Detection Probe PCR Kit was conducted using synthetic HBV DNA. The preliminary LoD was determined by testing a 10-fold dilution series in triplicates per concentration, and then confirmed with 20 replicates of the concentration determined to be the detectable LoD. The data revealed that the Hi-PCR® Hepatitis B Virus (HBV) Probe PCR Kit detects  $\approx 1$  copy/ $\mu\text{L}$ . Thus, the detectable Limit of Detection (LoD) was determined to be  $\approx 1$  copy/ $\mu\text{L}$ . The sensitivity analysis of the Hi-PCR® Hepatitis B Virus (HBV) Detection Probe PCR Kit was carried out on HiMedia's InstaQ 96 series, Biorad's CFX Series and Thermo Fisher's QuantStudio™ 5 Real-Time PCR System.

### Analytical Specificity

#### Inclusivity – In silico

The analytical specificity of the Hi-PCR® Hepatitis B Virus (HBV) Probe PCR Kit was ensured by performing *in silico* analysis of the HBV primers and probes using NCBI BLAST and optimizing the stringent PCR conditions. The detectability of all the relevant HBV subtypes and genotypes was ensured by analyzing the HBV primer-probes for sequence homology to the sequences available in the NCBI database using multiple sequence alignment tools.

### Analytical Reactivity

The analytical reactivity of the Hi-PCR® Hepatitis B Virus (HBV) Probe PCR Kit was verified by wet lab testing of the oligonucleotides (primers and probes) against commercially available controls - 4th WHO International Standard for HBV DNA for NAT NIBSC code: 10/266, 5th WHO International Standard for HBV DNA for NAT NIBSC code: 22/120 and PEI Reference Preparation HBV DNA (#3620/05).

### Cross-Reactivity

Wet testing was performed against the genomic or synthetic DNA/RNA of the pathogens (from ATCC) available in the laboratory on Bio-Rad CFX Opus 96, QuantStudio™ 5 (Thermo Fisher) and Insta Q96® Plus Real Time PCR Systems for any potential cross-reactivity. None of the tested pathogen in the below mentioned table showed any reactivity to the primers- probes of the Hi-PCR® Hepatitis B Virus (HBV) Probe PCR Kit.

Human immunodeficiency virus 1 (HIV-1) (VR- 3245SD)	Human parainfluenza virus 1 strain C35 (VR-94DQ)
Hepatitis A virus (VR-3257SD)	Plasmodium falciparum strain 3D7 (PRA-405)
Hepatitis E virus (VR-3258SD)	Plasmodium vivax DNA (PRA-3004SD)
Hepatitis B virus (VR-3232SD)	Quantitative Synthetic DNA from Plasmodium malariae (PRA- 3001SD)
Hepatitis C virus (VR-3233SD)	Genomic DNA extracted from Klebsiella pneumoniae (Strain No. BAAATCC2146)
Dengue virus (1-4) (VR-3228SD, VR-3229SD, VR-3230SD, VR-3231SD)	Genomic DNA extracted from Streptococcus pneumoniae strain (ATCC 49619)
Chikungunya virus (VR-3246SD)	Quantitative Genomic DNA from Staphylococcus epidermidis FDA strain PCI 1200 (12228DQ)
Human herpesvirus 2 (VR-540DQ)	Candida albicans strain SC5314 (MYA-2876DQ)
Quantitative Synthetic DNA from Human papillomavirus 16 (VR-3240SD)	Quantitative Genomic DNA from Escherichia coli (10798DQ)
Quantitative Synthetic DNA from Human papillomavirus 18 (VR-3241SD)	Genomic DNA extracted from Salmonella typhi (ATCC 14028)
Human coronavirus 229E (VR-740D)	Mycobacterium tuberculosis strain H37Ra (25177DQ)
Human adenovirus 1 strain Adenoid 71 (VR-1DQ)	Blood DNA

**Extraction kit compatibility:**

The following kits and systems are suitable for nucleic acid extraction:

Himedia Viral Purification Nucleic Acid kits MB582, MB575, MB582PC16, MB582MPF16, MB582MPF-32, MB582MPF-96, QIAamp MinElute Virus Kits and MagMAX™ Viral/Pathogen Nucleic Acid Isolation Kit. Alternative nucleic acid extraction systems and kits might also be appropriate. The suitability of the nucleic acid extraction procedure for use with Hi-PCR® Hepatitis B Virus (HBV) Probe PCR Kit has to be validated by the user.

**Warning**

Not for Medicinal Use.

**Precautions**

Read the procedure carefully before beginning the protocol. Wear protective gloves/protective clothing/eye protection/face protection. Follow good clinical laboratory practices while handling clinical samples. Standard precautions should be followed as per established guidelines. Safety guidelines may be referred to in safety data sheets of the product.

**Quality Control**

Each lot of Hi-PCR® Hepatitis B Virus (HBV) Probe PCR Kit is assayed for contaminating endonuclease, exonuclease, and non-specific DNase activities. It has been functionally tested in amplification assay.

**Limitations**

Strict compliance with the Instructions for Use is required for optimal results and the use of the kit is limited to staff qualified clinical laboratory personnel trained in the techniques of real-time PCR and in vitro diagnostic procedures. Appropriate specimen collection, transport, storage and processing procedures are required for the optimal performance of this test. This assay must not be used on the specimen directly. Viral DNA should be extracted from human plasma sample using appropriate nucleic acid extraction method. Presence of PCR inhibitors and other interferences may lead to false negative or invalid results. Although rare, mutations within the highly conserved regions of the targets genes covered by the kit's primers and/or probe may result in failure to detect the presence of pathogen. As with any diagnostic test, results of the Hi-PCR® Hepatitis B Virus (HBV) Probe PCR Kit need to be interpreted in consideration of all clinical and laboratory findings. Performance of the kit in monitoring treatment of HBV infection has not been evaluated.

**Troubleshooting Guide**

Sr. No.	Problem	Cause	Solution
1.	No amplification	Degraded samples	Check the integrity of DNA using agarose gel electrophoresis.
			Use freshly prepared DNA to ensure the availability of intact template sequence for efficient amplification.
		Error in protocol setup	Check whether all components are added in correct volume as per the manual.
		Inappropriate storage conditions	Store the reagents at recommended temperature for its optimal performance. Check expiry of the reagents and use new lot of reagents if necessary.
		Incorrect PCR programming	Ensure selection of appropriate fluorescence channel as detailed in the manual Compare the PCR program to the manual.

2.	Variability between replicates	Error in reaction set-up	Prepare a large volume master mix, vortex thoroughly and aliquot into reaction tubes.
		Air bubbles in reaction mix	Briefly centrifuge reaction samples/plate prior to running on a Real-Time PCR instrument.
		Pipetting error	C <sub>t</sub> values of replicates can show increased variation due to poor laboratory technique or imprecise pipettes. Use calibrated pipettes. Repeat the run.
3.	Amplification in negative template control	Cross contamination during handling	Replace all critical solutions. Repeat the analysis of all tests with fresh aliquots of critical reagents. Follow good laboratory practices to avoid contamination issues.

**Safety Information**

HiMedia’s Hi-PCR® Hepatitis B Virus (HBV) Probe PCR Kit for laboratory use only, not for drug, household or other uses. Take appropriate laboratory safety measures and wear gloves when handling.




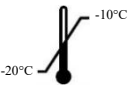




**Disposal**

User must ensure safe disposal by autoclaving and/or incineration of used or unusable preparations of this product. Follow established laboratory procedures in disposing of infectious materials and material that comes into contact with clinical sample must be decontaminated and disposed of in accordance with current laboratory.

**Technical Assistance**

At HiMedia, we pride ourselves on the quality and availability of our technical support. For any kind of technical assistance, mail at [mb@himedialabs.com](mailto:mb@himedialabs.com).

## Symbols

	Manufacturer		Do not use if package is damaged
	Batch code		Temperature limit
	Date of manufacture (YYYY-MM)		Consult instructions for use
	Use-by date (YYYY-MM)		Catalogue number

Identification No.: PIMBPCR149

Rev.No.: 06

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### Disclaimer :

User must ensure suitability of the product(s) in their application prior to use. Products conform solely to the information contained in this and other related HiMedia™ publications. The information contained in this publication is based on our research and development work and is to the best of our knowledge true and accurate. HiMedia™ Laboratories Pvt Ltd reserves the right to make changes to specifications and information related to the products at any time. Products are not intended for human or animal or therapeutic use but for laboratory, diagnostic, research or further manufacturing use only, unless otherwise specified. Statements contained herein should not be considered as a warranty of any kind, expressed or implied, and no liability is accepted for infringement of any patents.

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