

**MOLBIO DIAGNOSTICS LIMITED**  
**EN ISO 13485:2016 certified company**  
**CERTIFICATE OF ANALYSIS**

**Licence No.: MFG/IVD/2019/000018**

**Date: 29/12/2025**

**Document ID: COA/TN/HA018/50T**

<b>Product Name</b>	<b>Truenat® HAV</b>
<b>Generic Name</b>	<b>Chip-based Real Time PCR Test for Hepatitis A Virus</b>
<b>Lot No.</b>	<b>HA018</b>
<b>Set No.</b>	<b>NA</b>
<b>Mfg. Date</b>	<b>2025-05</b>
<b>Exp. Date</b>	<b>2027-04</b>
<b>Pack Size</b>	<b>50T</b>
<b>Storage condition</b>	<b>2°C to 30°C</b>

**PRECAUTION:** Refer Safety Data Sheet and Instructions for Use.

<b>Sr. No.</b>	<b>Components in each kit</b>	<b>Specification</b>	<b>Observation</b>
01	Number of pouches as per pack size	Should be present	Present
02	Pouches Contents: 1 chip, 1 micro tube, 1 desiccant pouch and 1 filter barrier tip	Should be present	Present
03	Colour of desiccant pouch	Should be present and Orange in Colour	Present / Orange Colour
04	Package Insert	Should be present	Present
05	Seal integrity test	Should pass	Pass

**Performance testing data**

<b>Samples</b>	<b>Ct Values</b>	
	<b>HAV</b>	<b>Control</b>
<b>Non Template Control</b>	ND	ND
<b>Negative Sample</b>	ND	27.73 ± 0.35
<b>Positive sample 1</b>	23.19 ± 0.11	26.10 ± 0.22
<b>Positive sample 2</b>	26.30 ± 0.32	25.56 ± 0.36
<b>Positive Sample 3</b>	30.12 ± 0.47	27.58 ± 0.85

ND – Not detected, Ct- Cycle threshold

\*Mfg- Manufacturing, Exp- Expiry

The lot is tested and verified as per QC Standards and is approved.



Name : Dr. Praveen Kumar MK  
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