



MOLBIO DIAGNOSTICS PVT. LTD.

An ISO 9001 & ISO 13485 Certified company

CERTIFICATE OF ANALYSIS

Mfg. Lic. No. : 3800/TEST/MFG/2017

Date: 16-11-2018

PRODUCT : Truenat™ HCV

LOT. NO. : THC28

MFG. DATE : 2018-10

EXP. DATE : 2020-09

PACK SIZE : 5T, 20T

STORAGE : 2°C to 30°C

A.R. NO. : B-THC-28

PRECAUTION: The product is offered without warranty for any other specific use than that specified in the Instructions for Use.

Sr. No.	Components in each kit	Specification	Observation
1	Pouch contains 1 chip, 1 micro tube, 1 desiccant pouch and 1 filter barrier tip	5 nos, 20 nos.	Pass
2	Colour of desiccant pouch	Blue	Pass
3	Package insert	01 no.	Pass

Performance			
Sr. No.	CONTROLS	Test Lot (Ct Values)	
Specificity Tests		HCV	IC
Negative Control		ND	30.38
Positive Control		28.33	27
		30.54	26.89
		29.38	26.83
		29	26.33
Standard deviation		± 0.92	± 0.29

*ND- Not detected

*A deviation of ≤ 1.5 is acceptable for Ct values

MANUFACTURING RECORDS ARE VERIFIED, CHECKED AND PRODUCT IS MANUFACTURED AS PER THE MASTER FORMULA, SAMPLES TESTED AND LOT IS QC APPROVED FOR EXAMINATION TEST OF ANALYSIS.



QUALITY CONTROL

Name: Dr. Praveen Kumar

Designation: QC Head

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