



MOLBIO DIAGNOSTICS PRIVATE LIMITED

ISO 13485:2016 certified company

CERTIFICATE OF ANALYSIS

Mfg. Lic. No. : MFG/IVD/2019/000018

Date:19/07/2022

Doc ID: COA/TN/ML018

BRAND NAME	Truenat® Malaria Pv/Pf		
GENERIC NAME	Chip-based Real Time Duplex PCR Test for Plasmodium vivax and Plasmodium falciparum		
LOT No.	ML018	CHIP LOT NO.	MGHW008
MFG. DATE	2022-07	EXP. DATE	2024-06
PACK SIZE	5T, 20T, 25T, 50T		
STORAGE	2°C to 30°C		A.R. No.:B-ML-018a

PRECAUTION: Refer Safety Data Sheet and Instructions for Use.


Sr. No.	Components in each kit	Specification	Observation
1	Pouch contains 1 chip, 1 micro tube, 1 dessicant pouch and 1 filter barrier tip	5 no, 20 no,25 no. 50 nos.	Pass
2	Colour of desiccant pouch	Orange	Pass
3	Package insert	01 no.	Pass

PERFORMANCE			
CONTROLS	Ct Values		
	Pv	Pf	Control
Specificity Tests			
Negative Control	ND	ND	27.4
Positive Control (Pv)	29.33	ND	26.14
Positive Control (Pf)	ND	30	28.8
Positive Control (Pv and Pf)	28.71	28.56	25.5
	28.29	28	24.6
Average	28.5	28.28	25.05
Standard deviation	+ 0.30	+ 0.40	+ 0.64

*ND- Not detected, Ct- Cycle threshold, Pv- Plasmodium vivax, Pf- Plasmodium falciparum

*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 SALE


QUALITY CONTROL
Name: Dr. Praveen Kumar
Designation: QC Head
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Molbio Diagnostics Private Limited

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