



MOLBIO DIAGNOSTICS PVT. LTD.

ISO 13485:2016 certified company

CERTIFICATE OF ANALYSIS

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

Date: 19/06/2020

BRAND NAME	Truenat™ Malaria Pf		
GENERIC NAME	Chip-based Real Time PCR Test for <i>Plasmodium falciparum</i>		
LOT No.	PF011		
MFG. DATE	2020-06		
EXP. DATE	2022-05		
PACK SIZE	5T, 20T		
STORAGE	2°C to 30°C		A.R. No. : B-PF-011

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 desiccant pouch and 1 filter barrier tip	5 no, 20 no.	Pass
2	Colour of desiccant pouch	Blue	Pass
3	Package insert	01 no.	Pass

PERFORMANCE		
CONTROLS	(Ct Values)	
Specificity Tests	FAL	Control
Negative Control	ND	30.17
Positive Control	28.5	30.6
	30.6	30.67
	28.6	31.57
	27.5	29.33
Standard deviation	± 1.29	± 0.92

*ND- Not detected, Ct- Cycle threshold, FAL- *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

Page 1 of 1

Molbio Diagnostics Private Limited

Regd. Office & Works: Plot No. L-46, Phase II D, Verna Industrial Estate, Verna - Goa 403 722. INDIA

Tel: +91-832-2783267 E mail: admin@molbiodiagnostics.com

Email: sales@molbiodiagnostics.com Website: www.molbiodiagnostics.com

CIN: U33125GA2000PTC002909 GSTN:30AACCM8275E1Z0