



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.	PF010
MFG. DATE	2020-06
EXP. DATE	2022-05
PACK SIZE	5T, 20T
STORAGE	2°C to 30°C
A.R. No. : B-PF-010	

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	29.5
Positive Control	28.5	30.17
	29.6	31.3
	28.2	29
	29	31.13
Standard deviation	± 0.61	± 1.05

*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


VERNA
QUALITY CONTROL
Name: Dr. Praveen Kumar
Designation: QC Head

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